



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

March 6, 2020

Re: Animal Welfare Assurance
A3143-01 [OLAW Case Z]

Dr. Camille P. Wicher
Vice President, Corp. Ethics and
Research Subject Protection
Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, NY 14263

Dear Dr. Wicher,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 2, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Roswell Park Cancer Institute. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Roswell Park Cancer Institute Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to euthanize a mouse in a timely manner resulting in unnecessary pain and distress of the animal. The final report states that LASR Attending Veterinarian notified the IACUC that a moribund mouse with severe abdominal distention needed to be euthanized. Dr. C was notified of the animal that afternoon, and after receiving no response the animal was humanely euthanized less than an hour later February 3, 2020 by LASR clinical veterinarian. The investigators (Drs. C and Z) were notified on January 30, 2020 that a mouse had abdominal distention and should be euthanized. Dr. C responded that afternoon by email that he would euthanize the animal, but the animal was ultimately euthanized on February 3rd as previously stated. It is also noted that Dr. C's failure to monitor tumor growth by measurement of abdominal circumference and body weight as stated in the protocol is also a non-compliance.

The IACUC sent a memo to the investigators on February 5, 2020 expressing concern regarding Dr. C's failure to euthanize the distressed mouse in a timely manner and his failure to monitor tumor growth. The committee requested a corrective and preventative plan of action (CAPA) to prevent recurrence of Dr. C's non-compliance. The plan was received on February 17, 2020 with additional clarifications provided on February 28, 2020. The CAPA for Dr. C includes the following:

- Retaking AALAS online training courses and quizzes.
- Retaking LASR WetLab for working with the laboratory mouse.
- Supervision by a senior lab member when enrolling mice on an experiment.
- Requirement to re-read IACUC protocol, including amendments and sign an affidavit stating so.

- Discuss and review body scoring procedure, its importance and signs of animal distress and humane endpoints with senior lab member.
- Assessment of each mouse entered into study by Dr. C with use of body scoring and body score cage card.
- Notice that additional animal welfare violations by Dr. C will justify removal from Dr. Z's protocol.
- Biannual reviews of the protocol during in-person meetings among all personnel performing substantial work on the protocol and these reviews will be documents.

The report states that Dr. C has completed online AALAS training, reviewed Body Scoring SOP, has reviewed with senior lab member body scoring procedures and signs of distress and has signed the affidavit affirming these actions on February 28, 2020.

It is noted this project was not supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the Roswell Park Cancer Institute has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 3, 2020 7:15 AM
To: Wicher, Camille; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Moser, Michael
Subject: RE: Reports of non-compliance

Good morning Dr. Wicher,

Thank you for the reports. We will send an official response soon.

Kind Regards,

Jacquelyn Tubbs, DVM, DACLAM
 Veterinary Medical Officer
 Office of Laboratory Animal Welfare
 National Institutes of Health

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From: Wicher, Camille <Camille.Wicher@RoswellPark.org>
Sent: Monday, March 2, 2020 4:20 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Moser, Michael <Michael.Moser@RoswellPark.org>
Subject: Reports of non-compliance

Please find two reports of non-compliance. Thank you.

Camille P. Wicher, Ph.D., Esq. MSN, RN
 Assistant Professor of Oncology
 Vice President
 Roswell Park
 Elm & Carlton Sts.
 Buffalo, New York 14263

(b) (6)



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Camille P. Wicher, Ph.D. Esq., RN, MSN.
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Roswell Park Cancer Institute
Elm & Carlton Sts
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March 2, 2020

Axel Wolff, DVM.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Reports of Non-Compliance
OPRR Assurance #A-314301.
USDA Regis. #21-R-032

Dear Dr. Wolff,

Please accept the enclosed reports as required by 9 CFR 2.31 (c) (3) and (d) (7) Subchapter A of the Animal Welfare Act, as well as PHS Policy IV.F.3.

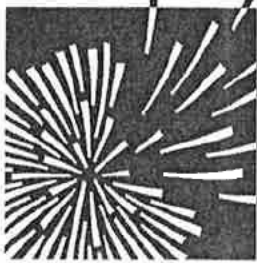
Corrective action has been instituted as per the attached document. Roswell Park Cancer Institute is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions, please do not hesitate to contact me at (b) (6)

Thank you in advance for your cooperation in this matter.

Sincerely,

(b) (6)

Camille P. Wicher, PhD., Esq., RN, MSN
Vice President
Institute Official



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COMPREHENSIVE CANCER CENTER

Michael T. Moser, Ph.D.
Chair Institutional Animal Care and Use
Committee (IACUC)
A457 Carlton House
Buffalo, NY 14263
Phone: 716 845-1155
FAX: 716 845-1258
Mike.Moser@roswellpark.org

(b) (6)

To: Camille Wicher, Ph.D., RPCI Institute Official
From: Michael T. Moser, Ph.D., Chair RPCI IACUC
DATE: February 28, 2020
Re: Non-Compliance with IACUC protocol 1386M and Moribund Mouse in M482

This is to report a non-compliance animal welfare incident that occurred on February 3, 2020. Dr. Sandra Sexton, LASR Attending Veterinarian notified IACUC that a moribund mouse (b) (4) protocol 1386M) with a severe abdominal distension needed to be euthanized. Dr. C was notified of this at 2:34 the afternoon of February 3, 2020 (e-mail (b) (6)). After receiving no response from Dr. C, the mouse was humanely euthanized by LASR (b) (6) (b) (6) later that afternoon (~3:20 p.m.).

Upon review of the incident by IACUC and LASR Veterinary Services, additional information regarding this mouse was obtained. The mouse was housed in (b) (4) Rack 4 cage E5 and there were two other healthy mice in the cage. Drs. C and Z were originally notified by LASR Veterinary Services on Thursday January 30, 2020 that this particular mouse had abdominal distension and should be euthanized (e-mail (b) (6) 10:58 a.m.). It was also noted that there was no documentation of measurement of abdominal circumference of this mouse since December 23, 2019. The mouse had been implanted with ID8 ovarian tumor cells IP and the protocol requires weekly measurement of abdominal circumference and body weight as criteria for Body Condition Scoring for Intra-Abdominal Tumors. Dr. C responded that afternoon by e-mail (2:11 p.m.) that he would euthanize the mouse. Dr. C failed to euthanize the mouse. As stated above (b) (6) euthanized the mouse on the afternoon of Monday February 3rd. The IACUC believes that Dr. C's failure to euthanize the mouse in a timely manner caused unnecessary pain and distress to the mouse. In addition, Dr. C's failure to monitor tumor growth by measurement of abdominal circumference and body weight as stated in the protocol 1368M is also non-compliance with protocol 1368M.

IACUC sent a memo to Drs. Z and C on February 5, 2020 expressing concern regarding Dr. C's failure to euthanize the distressed mouse in a timely manner and his failure to routinely monitor and document monitoring of the mouse with a distended abdomen as per protocol 1386M. Dr. C should have been appropriately monitoring the mouse for moribund and scientific endpoints and following the body scoring frequency stated in the protocol. LASR Veterinary Services should not have had to notify Dr. C that animals need to be euthanized.

The IACUC requested a corrective and preventative plan of action (CAPA) to prevent recurrence of Dr. C's non-compliance with protocol 1386M (IACUC memo 02/05/2020). The CAPA was received from (b) (6) (approved personnel on 1386M) on behalf of Dr. Z on February 17, 2020 with additional clarifications provided on February 28, 2020. The CAPA (see attached) stated the following:

1. Dr. C will retake AALAS online training courses and quizzes.
2. Dr. C will retake the LASR WetLab for working with the laboratory mouse.
3. Dr. C will be supervised by a senior lab member (b) (6) when enrolling mice on an experiment. Dr. C will seek assistance by a co-worker listed on 1386M when he is unable to monitor, score or euthanize his mice. Two additional personnel were added to 1386M (Request to change personnel form submitted 02/10/2020 approved 02/11/2020). If necessary, Veterinary Services may be asked to euthanize moribund mice on 1386M if laboratory

personnel (approved for 1386M) cannot immediately respond to a LASR Veterinary Services request to euthanize.

4. Dr. C will be required to re-read IACUC protocol 1386M, including all amendments and sign an affidavit stating so. (see attached)
5. Body Scoring procedure, importance of Body Scoring and signs of animal distress and humane endpoints will be discussed and reviewed with Dr. C by (b) (6)
6. To assure mice will not suffer undue stress due to abdominal distension, each mouse entered into study by Dr. C will be assessed as per LASR SOP 12.7 for Body Scoring and as specified in 1386M and by using a Body Score Cage Card.
7. Additional animal welfare violations by Dr. C will justify removal from Dr. Z' IACUC protocol 1386M.
8. There will be biannual reviews of 1386M during in-person meetings among all personnel performing substantial work on the protocol and these reviews will be documented).

Dr. C completed the online AALAS training and quizzes, reviewed the Body Scoring SOP, has reviewed with (b) (6) body scoring procedures and signs of distress and has signed the attached affidavit affirming these actions on 02/28/2020. This was not a PHS funded project.

The IACUC committee feels that Dr. Z' CAPA addresses sufficiently the root causes, the corrective plan needed and the preventative processes to prevent a recurrence of this non-compliance by Dr. C. The IACUC believes that Dr. C understands the importance of following animal protocols, properly performing body scoring, timely response(s) to a LASR Veterinary Services request(s), and the signs of pain and distress in laboratory mice. The IACUC believes this an animal welfare concern and therefore may be reportable. If you have any additional questions, require clarification or further action by the IACUC please feel free to contact me.